UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: April 30, 2012

Subject: Clopyralid: Occupational Exposure Assessment for a New Use on Apples; Expansion of Crop Group 5B; and Revised Residential Exposure Assessment for Use on Turf.

PC Code: 117401	DP. No.: D391748
Petition No.: 1E7882	EPA Reg. No. 62719-73
Decision No.: 450262	Reg. Action: Section 3
Assessment Type: Occupational and Residential	CAS No.: 57754-85-5
TXR No.: NA	Case No.: NA
MRID No.: None	40 CFR: §180.431

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ACTION REQUESTED

The Interregional Research Project No. 4 (IR-4) has petitioned the Agency to register a new use for the herbicide clopyralid to control weeds in apple orchards and to expand the list of crops in Crop Group 5B. It is Health Effects Division (HED) policy to use the best available data to assess handler exposure in the absence of chemical-specific data. Some of these data are proprietary (e.g., Agricultural Handler Exposure Task Force [AHETF] data), and subject to the data protection provisions of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on April 5, 2012.

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I. EXECUTIVE SUMMARY

BACKGROUND: Clopyralid is a herbicide used for management of broadleaf weeds. It is currently registered for use on food crops, ornamentals, and turf. The end-use product, Stinger® Herbicide (EPA Reg. No. 62719-73), is formulated as an emulsifiable concentrate (EC) which contains 40.9% monoethanolamine salt of clopyralid acid at 3.0 lb acid equivalent (AE)/gal.

The IR-4 has submitted a petition proposing the use of clopyralid to control broadleaf weeds in apple orchards and to add the new use to the Stinger® Herbicide label. The registrant, Dow AgroSciences LLC has submitted a supplemental label incorporating changes to the Stinger® Herbicide label. Although IR-4 also submitted a petition for use of Stinger® Herbicide to control weeds in Brassica (cole) and leafy vegetables (Crop Group 5), HED had previously performed an occupational exposure assessment on mustard greens and the estimated risk was not of concern (MOE =58,000 with a level of concern of 100 (S. Wang, D270507, 9/26/02). A separate occupational exposure assessment is not required for the proposed use expansion on Brassica and leafy vegetables since a) mustard greens are classified within Crop Group 5, b) the previously assessed application rate was equal to the proposed rate for Brassica and leafy vegetables, and c) no occupational exposure scenarios resulted in risks of concern.

USE PATTERN: The recommended application methods for apple orchards consist of either direct broadcast spray to the orchard floor on each side of the apple tree row in a minimum of 10 gallons of water per acre using ground equipment or spot treatment using hand held equipment. The proposed maximum single application rate is 0.25 lb AE/A, but up to 2 applications can be made per season as long as the seasonal rate of 0.25 lb AE/A is not exceeded. The preharvest interval for apple is 30 days. Based on the use pattern, the duration of exposure for occupational handlers is expected to be short- term (1 to 30 days) and intermediate-term (1 to 6 months). Long-term exposures (greater than 6 months) are not anticipated.

HAZARD CHARACTERIZATION: Technical clopyralid acid has a low acute oral toxicity (Toxicity Category IV). It is a severe eye irritant (Toxicity Category I), but is a low irritant to the skin (Toxicity Category IV). It has moderate acute dermal and inhalation toxicities (Toxicity Category III). It is not a dermal sensitizer. No systemic toxicity was observed in a 21-day dermal study in rabbits even at the limit dose of 1,000 mg/kg/day; therefore, a dermal point of departure (POD) was not selected. Inhalation PODs of 75 and 15 mg/kg/day were selected from a rat oral study for short- and intermediate-term exposures, respectively. Since an inhalation study was not available, toxicity by the inhalation route was considered to be equivalent to toxicity by the oral route of exposure. Furthermore, since the inhalation endpoint was not sex specific, the average adult body weight of 80 kilograms was used to estimate inhalation exposure.

There was no evidence of increased pre- and/or postnatal qualitative or quantitative susceptibility in the developmental rat or rabbit studies or in the rat 2-generation reproduction study. Therefore, the required 10X Food Quality Protection Act (FQPA) safety factor was reduced to 1x. Based on available studies, HED has classified clopyralid as "not likely to be carcinogenic to humans." HED's level of concern (LOC) for clopyralid is a margin of exposure (MOE) of 100 for all residential and occupational scenarios.

OCCUPATIONAL HANDLER EXPOSURE: No chemical-specific handler exposure data were submitted in support of this registration. It is HED policy to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1), and the AHETF database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. Default assumptions established by the HED ExpoSAC were used for parameters such as body weight and acres treated and amount handled per day. Occupational handler assessments are based only on inhalation exposures. No dermal exposures for handlers were estimated based on a lack of a dermal POD. The estimated short-term inhalation risks to handlers are not of concern with MOEs ≥880,000 at the baseline level of personal protective equipment (PPE), consisting of long-sleeved shirt and long pants and shoes plus socks. Further, for intermediate-term exposure, MOEs were ≥180,000 assuming baseline PPE.

OCCUPATIONAL POSTAPPLICATION EXPOSURE: Postapplication workers may be exposed to residues of clopyralid through dermal and inhalation routes if they enter treated fields to perform postapplication activities, such as weeding, irrigation, scouting, etc. Postapplication dermal exposure is not of concern since there is no hazard associated with exposure to clopyralid via the dermal route. Although there is potential for postapplication inhalation exposure, a quantitative postapplication inhalation exposure assessment was not performed. However, an inhalation exposure assessment performed for occupational/commercial handlers was found to be not of concern and this exposure is likely to result in higher risk than postapplication exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of occupational postapplication inhalation exposure scenarios.

RESTRICTED ENTRY INTERVAL: The submitted parent label for Stinger® Herbicide is for a monoethanolamine salt of clopyralid acid and has a restricted entry interval (REI) of 12 hours which is appropriate. The clopyralid acid however, is a severe eye irritant (Acute Toxicity Category I) and end-use formulations containing the acid require a REI of 48-hours.

RESIDENTIAL HANDLER AND POSTAPPLICATION EXPOSURES: Several formulations of clopyralid are currently registered for weed control on lawns, turf, and ornamentals in residential and public areas. Although no new residential uses of clopyralid are being proposed with this submission, a previous residential exposure assessment was updated to incorporate the revisions to the Standard Operating Procedures for Residential Exposure Assessment (Residential SOPs, 2012). Scenarios assessed included inhalation exposure for residential handlers, and postapplication oral exposure for children playing on treated lawns. Note that only short-term exposure durations were assessed for residential handlers and for postapplication exposure to children playing on treated lawns. All residential handler and postapplication scenarios resulted in MOEs ≥100 and were not of concern.

CONCLUSIONS: Since the occupational handler and postapplication exposures and risks for clopyralid resulting from the proposed new use do not exceed HED's level of concern, there are no occupational exposure issues that prevent registering clopyralid for use on apple. Further, there are no risks of concern associated with the existing use on turf. The request to expand Crop Group 5B by adding Brassica, leafy greens, without any change to the approved use

pattern, has no Occupational and Residential Exposure (ORE) issues that would prevent approval of the proposed label amendment.

In accordance with the updated Part 158 data requirements (2007), chemical-specific dislodgeable foliar residue (DFR) and turf transferable residue (TTR) data are required for clopyralid based on its agricultural and turf uses. However, since there's no detectable toxicity associated with the dermal route, the DFR study is not needed; further, since the only exposure for children is via the oral route from playing on treated turf, and the MOEs are greater than 10,000 and therefore, a TTR study is not needed (Hazard and Science Policy Council [HASPOC], TXR 0056270, 3/29/2012).

HUMAN SUBJECTS STUDIES

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from the PHED Version 1.1; the AHETF database; and other registrant-submitted exposure monitoring studies (MRID 44339801), are subject to ethics review pursuant to 40 CFR 26, have received that review, and are compliant with applicable ethics requirements. For certain studies that review may have included review by the Human Studies Review Board (HSRB). Descriptions of data sources as well as guidance on their use can be found at: http://www.epa.gov/pesticides/science/handler-exposure-data.html and http://www.epa.gov/pesticides/science/post-app-exposure-data.html.

II. INTRODUCTION

Clopyralid (3,6-dichloro-2-pyridinecarboxylic acid, monoethanolamine salt) is registered for the control of annual and perennial broadleaf weeds on a number of agricultural crops, turf, and on non-crop and fallow lands.

The IR-4 has submitted a petition to add a new use for clopyralid herbicide on apple for controlling postemergence broadleaf weeds. The registrant, Dow AgroSciences LLC has submitted a Supplemental label of Stinger® Herbicide (EPA Reg. No. 62719-73) for this purpose. The Stinger® Herbicide is an EC formulation containing 40.9 % monoethanolamine salt of clopyralid acid at 3.0 lb AE/gal. The petitioner has also requested additional label amendments to expand the list of crops allowed on the label for Crop Group 5B without any change to the approved use pattern.

III. PROPOSED USE PATTERN

The proposed maximum single application rate for Stinger® Herbicide on apple is 0.25 lb AE/A, which is also the maximum seasonal rate. The proposed label indicates 1 or 2 applications may be made per season as long as the seasonal rate of 0.25 lb AE/A is not exceeded. Although a pre-harvest interval (PHI) of 30 days is specified, the label does not provide a recommended re-treatment interval (RTI). The recommended application method is soil-directed broadcast spray using groundboom equipment. The parent label also recommends spot and band treatments using hand held sprayers. The proposed use pattern is summarized in Table 1.

The PPE for applicators and other handlers in the registered Stinger® Herbicide label is baseline clothing (long-sleeved shirt, long pants, and shoes plus socks), chemical-resistant gloves made of any waterproof material, and protective eyewear.

Table 1. Proposed Use Pattern for Clopyralid on Apples.

Use Site	Application Methods	Single Appl. Rate (lb AE/A)	Max. Number of Appl. / Season	Max. Seasonal Rate (lb AE/A)	Preharvest Interval
Apple	Groundboom and backpack sprayers	0.094 - 0.25	2	0.25	30 days

Since expansion of the crops allowed on the Stinger® Herbicide label by adding Brassica leafy greens to Crop Group 5B is being proposed without any change to the registered use pattern for Crop Group 5B, a separate occupational exposure assessment is not required to support the proposed label amendment.

IV. HAZARD CHARACTERIZATION

Technical clopyralid acid has a low acute oral toxicity (Toxicity Category IV). It is a severe eye irritant (Toxicity Category I), but is a low skin irritant (Toxicity Category IV). It has moderate acute dermal and inhalation toxicities (Toxicity Category III). It is not a dermal sensitizer (Table 2).

Table 2. Acute Toxicity Profile for Clopyralid [1]				
Guideline Number	**Study Type Classification**	**MRID Number**	**Results**	**Toxicity Category**
870.1100	Acute-oral-rat	41641301	LD_{50} (M/F) >5,000 mg/kg	IV
870.1200	Acute-dermal-rat	41641302	LD_{50} (M/F) > 2000 mg/kg	III
870.1300	Acute-inhalation-rat	41848301	LC_{50} (M/F) > 1 mg/L	III
870.2400	Acute-eye irritation-rabbit	41641304	Severe irritation at 7 days (corrosive)	I
870.2500	Acute-dermal irritation-rabbit	41641305	Not an irritant	IV
870.2600	Skin sensitization - guinea pig	41641306	Not a sensitizer	-

1. This acute toxicity profile is for clopyralid acid. The Stinger® Herbicide (EPA Reg. No. 62719-73) is the monoethanolamine salt of clopyralid acid and is made by an integrated system.

There are sufficient toxicity data available to conduct a occupational, residential, and human health risk assessment for clopyralid and the database is considered complete. HED concluded that additional studies previously considered to be required to support conditional registration of clopyralid were not needed based on weight of the evidence considerations. These studies included the acute and subchronic neurotoxicity studies and the 28-day inhalation toxicity study; the required immunotoxicity studies were submitted and demonstrated no concern for immunotoxicity associated with clopyralid. The PODs, endpoints and uncertainty factors selected for ORE assessment are summarized in Table 3.

Table 3. Toxicological Doses and Endpoints for Clopyralid for Use in Residential and Occupational Human Health Risk Assessments.

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral, Short-term (1-30 days)	NOAEL= 75 mg/kg/day	UF_A= 10X UF_H= 10X FQPA SF =1X	Residential LOC for MOE= 100	Developmental Toxicity (oral) - rat Maternal LOAEL = 250 mg/kg/day, based on decreased body weight gain and food consumption during GD 6-9.
Dermal, Short-and Intermediate-term (1-30 days and 1-6 months, respectively)	No dermal or systemic toxicity was observed at the limit dose (1000 mg/kg/day) in a rabbit 21-day dermal toxicity study and there are no developmental or reproductive concerns. Therefore, a POD could not be selected to estimate dermal exposure.			
Inhalation, Short-term (1-30 days)	Oral study NOAEL = 75 mg/kg/day (inhalation toxicity assumed to be equivalent to toxicity via the oral route)	UF_A= 10X UF_H= 10X FQPA SF =1X	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental Toxicity (oral) – rat Maternal LOAEL = 250 mg/kg/day, based on decreased body weight gain and food consumption during GD 6-9.
Inhalation Intermediate-term (1-6 months)	Oral study NOAEL= 15 mg/kg/day (inhalation toxicity assumed to be equivalent to toxicity via	UF_A= 10X UF_H= 10X FQPA SF =1X	Residential LOC for MOE= N/A (only short-term exposure is expected in residential settings.	2-Year Combined Chronic Toxicity/Carcinogenicity (oral) – rat LOAEL = 150 mg/kg/day, based on increased epithelial hyperplasia and thickening of the limiting ridge of the stomach in both sexes.

Table 3. Toxicological Doses and Endpoints for Clopyralid for Use in Residential and Occupational Human Health Risk Assessments.				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
	the oral route)		Occupational LOC for MOE = 100	
Cancer (all routes)	"Not likely to be carcinogenic to humans". Cancer risk is not of concern.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. MOE = margin of exposure. LOC = level of concern.

There was no evidence of increased pre- and/or postnatal qualitative or quantitative susceptibility in the developmental rat or rabbit studies or in the rat 2-generation reproduction study. Therefore the required 10X FQPA SF was reduced to 1x. There were no treatment-related increases in tumor incidence in the 2-year rat and mouse oral studies which included a high dose that exceeded the limit dose. Genotoxicity studies were also negative. Therefore, the Agency has classified clopyralid as "not likely to be carcinogenic to humans." HED's LOC for clopyralid is an MOE of 100 for residential and occupational scenarios and MOEs ≥ 100 do not exceed HED's level of concern. For a more detailed hazard characterization, a recent risk assessment on clopyralid is available (M. Doherty, D361316, 12/3/09).

Note that for both occupational and residential handlers, a body weight of 80 kg should be used for exposure calculations because the inhalation endpoints were based on non-sex-specific effects.

V. OCCUPATIONAL HANDLER EXPOSURES

1. Exposure Characterization

The proposed use pattern for apples (Table 1) is expected to result in short-term (1-30 days) exposure for most handlers. However, since commercial applicators may apply Stinger® Herbicide at several locations during the crop season, intermediate-term (1-6 months) handler exposure could occur, and therefore an intermediate-term assessment was also conducted.

Potential Exposure Scenarios: Exposure scenarios describe the handler activities (mixer, loader and applicator) and type of application equipment. Based on the proposed use pattern, the following exposure scenarios were identified:

- mixing of EC formulation and loading diluted spray in groundboom sprayer
- applying the spray using groundboom equipment
- mixing, loading and applying the EC formulation using a back-pack sprayer for spot treatment.

2. Occupational Handler Exposure and Risk

The registrant has not submitted a chemical-specific exposure study to select unit exposures required for estimating handler exposure. It is HED policy to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include the PHED Version 1.1, AHETF, Outdoor Residential Exposure Task Force (ORETF) databases, or other registrant-submitted occupational exposure studies. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as "unit exposures", are outlined in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (http://www.epa.gov/opp00001/science/handler-exposure-table.pdf), which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html.

Other inputs from ExpoSAC's Policy No. 9.1 (Standard Values of Daily Acres Treated) were used to estimate handler exposure. Regardless of what the proposed label stipulates for PPE, HED typically conducts an initial assessment at the baseline level of personal protection consisting of a long-sleeve shirt, long pants, shoes and socks (i.e., no gloves), and no respirator. Additional PPE and mitigation measures, such as gloves, respirators, engineering, and administrative controls are added if required, to obtain a risk level that does not exceed HED's LOC.

Table 4 summarizes the short- and intermediate-term inhalation risk estimates for handlers resulting from the proposed use of Stinger® EC Herbicide on apples applied as broadcast and spot treatments. No dermal endpoint and dose were selected for clopyralid for dermal exposure; therefore, dermal exposure for handlers was not estimated. The results of HED's assessments indicate that at baseline PPE (no respirator), the short-term (MOE $\geq$ 880,000) and intermediate-term inhalation (MOE $\geq$ 180,000) risk estimates are significantly above HED's LOC of an MOE of 100, and are not of concern.

Table 4. Occupational Handler Inhalation Exposure and Risk Estimates from Applying Clopyralid in Apple Orchards.							
Handler Scenario Used for Apple [1]	**Application Rate [2]**	**Area Treated or Gallons Used/day [3]**	**Risk Mitigation Level [4]**	**Inhalation Unit Exp. (µg/lb ae) [5]**	**Inhalation Dose (mg/kg/day) [6]**	**Short- term Inhalation MOE [7]**	**Interm.-term Inhalation MOE [8]**
Mixing/Loading Liquids for Groundboom (AHETF)	0.25 lb ae/A	80 acres	Baseline	0.219	5.5E-5	1,400,000	270,000
Applying by Groundboom (AHETF)	0.25 lb ae/A	80 acres	Baseline	0.34	8.5E-5	880,000	180,000
Mixing/Loading/Applying by backpack Sprayer (MRID 44339801) (ground-directed - orchards)	0.025 lb ae/gal)	40 gals	Baseline	2.58	3.2E-5	2,300,000	470,000

1. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table used for each scenario is indicated in parenthesis.
2. The parent label (62719-73 recommends a minimum spray volume of 10 gal/A for ground application and therefore, for back-pack sprayer, application rate was calculated as 0.25 lb ae/A/10 gal/A = 0.025 lb ae/gal.
3. Area treated per day assumptions are from ExpoSAC (SOP No. 9.1).
4. Baseline PPE includes long-sleeved shirt, long pants, shoes and socks, and no respirator.
5. From http://www.epa.gov/pesticides/science/handler-exposure-data.html
6. Inhalation Dose (mg/kg/day) = [Appl. Rate (lb ae/A or lb ae/gal) * Area Treated/day (acres or spray volume) * Inhal. Unit Exp. (µg/lb ae/1000) * Inhalation Absorption (100%)] / Body Wt (80 kg).
7. Short-term Inhalation MOE = Short-term NOAEL (75 mg/kg/day) / Inhalation Dose (mg/kg/day).
8. Intermediate-term Inhalation MOE = intermediate-term NOAEL (15 mg/kg/day) / Inhalation Dose (mg/kg/day).

VI. OCCUPATIONAL POSTAPPLICATION EXPOSURES

Postapplication workers may be exposed to residues of clopyralid through dermal and inhalation routes when they enter treated areas to perform postapplication activities, such as thinning, irrigation, scouting, etc. Since there's no systemic toxicity associated with dermal exposure to clopyralid, a dermal postapplication exposure assessment was not conducted.

Based on the Agency's current practices, a quantitative postapplication inhalation exposure assessment was not performed for clopyralid at this time primarily because of the low acute inhalation toxicity (Toxicity Category IV) of the end-use product formulation (M. Hashim, D291712, 10/16/2003), and the low proposed use rate (0.25 lb ae/A). However, there are multiple potential sources of postapplication inhalation exposure to individuals performing postapplication activities in previously treated fields. These potential sources include volatilization of pesticides and re-suspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency is in the process of evaluating the SAP report as well as available postapplication inhalation exposure data generated by the Agricultural Reentry Task Force and may, as appropriate, develop policies and procedures, to identify the need for and, subsequently, the way to incorporate occupational postapplication inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational postapplication inhalation exposure assessment for clopyralid.

Although a quantitative occupational postapplication inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers. Handler exposure resulting from application of pesticides to crops is likely to result in higher exposure than exposure to workers if they enter treated fields. Therefore, it is expected that the handler inhalation exposure estimates would be protective of most occupational postapplication inhalation exposure scenarios.

Restricted Entry Interval (REI)

The registrant has provided Supplemental labels for Stinger® Herbicide (EPA Reg. No. 62719-73) with this submission. The active ingredient in Stinger® is the monoethanolamine salt of clopyralid acid and has a 12-hour REI which is appropriate. The clopyralid acid however, is a severe eye irritant (Acute Toxicity Category I) and its end-use product formulations carry a REI of 48-hours.

VII. RESIDENTIAL AND NON-OCCUPATIONAL EXPOSURES

No new residential uses for clopyralid are being proposed at this time. However, for the purpose of performing an aggregate human health risk assessment, the residential exposures and risks estimated previously were updated in accordance with the Revised Standard Operating Procedures for Residential Exposure (Residential SOPs, 2012).

RESIDENTIAL EXPOSURES AND RISKS

Several formulations of clopyralid are registered for weed control on residential lawns and/or professionally maintained turf areas. Previously, HED had reviewed two formulations of clopyralid for residential exposures: Lawn Fertilizer Plus Confront® Weed Control (EPA Reg. No. 62719-263), a granule plus fertilizer mix containing 0.18 % clopyralid (0.12 % ae) and Lontrel* Turf and Ornamental (EPA Reg. No. 62719-305), an EC formulation containing 40.9 % clopyralid (or 3.0 lb ae/gal). The granule has an application rate of 15.55 lbs of product per 4,500 sq. ft. (0.19 lb AE/A) and the EC has a maximum single application rate of 1⅓ pt./A (0.5 lb ae/A) on turf. The updated exposure and risk estimates are summarized in Table 5.

Residential Handler Exposure

Based on the use pattern of clopyralid on home lawns, it is expected that homeowners are exposed for a short-term duration only. A short-term dermal residential handler exposure assessment was not conducted due to the lack of toxicity via the dermal route. The estimated short-term inhalation handler MOEs ranged from 3.4E+5 to 2.4E+7 and since all scenarios resulted in estimated MOEs greater than 100, there are no risks of concern associated with residential handler exposure (Table 5).

Table: 5. Summary of Residential Handler Exposure and Risk Estimates for Clopyralid.[1]

Exposure Scenario	Application Rate [2]	Area Treated or Gallons Used/Day) [3]	Unit Exp. (mg/lb ae) [3]	Short-term Inhalation	
				Dose (mg/kg/day) [4]	MOE [5]
Granule: Applied with push-type spreader	0.19 lb ae/A	0.5 A	0.0026	3.1E-6	2.4E+7
EC: Mixing and applying spray with hose-end sprayer	0.5 lb ae/A	0.5 A	0.022	6.9E-5	1.1E+6
EC: Mixing and applying spray with back-pack sprayer	0.025 lb ae/gal	5 Gallons	0.14	2.2E-4	3.4E+5
EC: Mixing and applying with manually pressurized handwand sprayer	0.025 lb ae/gal	5 Gallons	0.018	2.8E-5	2.7E+6

1. The previous estimate (S. Wang, D270507, 9/26/2007) was recalculated using unit exposures and area treated from the revised Residential SOP (2012).
2. Application rate is expressed either in lb ae/A or in lb ae/gal. The EC formulation (Lontrel Turf and Ornamental, (EPA Reg. No. 62719-305) recommends a minimum spray volume of 20 gal/A. Therefore, for back-pack and handwand sprayers, the application rate was calculated in lb ae/gal (0.5 lb ae/A/20 gal=0.025 lb ae/gal).
3. Area treated/A or spray vol. used/day assumptions are from the Lawn and Turf, Residential SOP (2012).
4. Inhalation Dose (mg/kg/day) = [Appl. Rate (lb ae/A or lb ae/gal) * Area Treated/day (acres or spray volume * Inhal. Unit Exp. (mg/lb ae) * Inhalation Absorption (100%)] / body wt (80 kg).
5. Short-term Inhalation MOE = Short-term NOAEL (75 mg/kg/day) / Inhalation Dose (mg/kg/day).

Residential Postapplication Exposure

Note that only the short-term exposure duration was assessed for residential postapplication

exposure to children playing on treated lawns. There is no short-term dermal endpoint and dose established for clopyralid, and therefore dermal postapplication exposure to children and adults was not assessed. There is a potential for postapplication inhalation and oral exposure to children when they play on treated lawns, and the nature and quantity of these exposures are discussed below.

Residential Postapplication Inhalation Exposure: Based on the Agency's current practices, a quantitative residential postapplication inhalation exposure assessment was not performed for clopyralid at this time, primarily because of the low acute inhalation toxicity (Toxicity Category IV) of the end-use product. However, volatilization of pesticides may be a source of postapplication inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html). The Agency is in the process of evaluating the SAP report and may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate postapplication inhalation exposure into the Agency's risk assessments. If new policies or procedures are developed, the Agency may revisit the need for a quantitative postapplication inhalation exposure assessment for clopyralid.

Residential Postapplication Oral Exposure: There is a potential for postapplication oral exposure (i.e., hand to mouth, object to mouth, and soil and granule ingestion) for children following use of clopyralid granules and liquids on recreational and home lawns. All MOEs ranged from 10,000 to more than 4 million, and are not of concern. A summary of the oral risk estimates is provided in Table 6.

Table: 6. Summary of Children's Postapplication Exposure and Risk Estimates for Clopyralid.[1]

Formulation Type	Exposure Scenario	Application rate lb/AE/A	Short-term incidental oral	
			Dose (mg/kg/day) [2]	MOE [3]
EC	Hand-to-mouth	0.5	0.00745	10,000
	Objects-to-mouth	0.5	0.00023	330,000
	Soil ingestion	0.5	0.000016	4,600,000
Granule	Hand-to-mouth	0.19	0.00028	270,000
	Objects-to-mouth	0.19	0.00009	860,000
	Granule ingestion (episodic)	-	-	Not applicable [4]

1. Revised S. Wang (D270507, 9/26/2007) estimates based on new Residential SOP for Exposure (2012).
2. Oral doses were calculated based on new Residential SOP for Exposure (2012).
3. Short-term incidental oral MOE = NOAEL 75 (mg/kg/day) / oral dose (mg/kg/day).
4. There is no acute dietary endpoint for clopyralid. Therefore, exposure from granule ingestion was not assessed.

Residential Combined Exposure

HED believes that combining children's postapplication exposures, such as hand-to-mouth, object-to-mouth, and soil and granule ingestion resulting from EC and granule formulations of clopyralid on home lawns would be overly conservative. Although these exposures may occur

simultaneously based on the use pattern of the pesticide and the behavior associated with the exposed population, the inputs used in calculating the risk estimates are conservative, and combining these conservative exposure and risk estimates would result in an unrealistic estimate of actual exposure and risk. In the case of clopyralid on turf, the scenario with the highest oral exposure for children (hand-to-mouth, MOE=10,000) is considered protective of all children's postapplication exposure and risk, and should be used in the aggregate exposure and risk calculations.

VIII. SPRAY DRIFT

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application methods employed for clopyralid. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices (see the Agency's Spray Drift website for more information at http://www.epa.gov/opp00001/factsheets/spraydrift.htm). On a chemical by chemical basis, the Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift with specific products with significant risks associated with drift.

IX. REVIEW OF HUMAN RESEARCH

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from the PHED (1.1); AHETF; ORETF; and the Agricultural Re-entry Task Force (ARTF) databases, are subject to ethics review pursuant to 40 CFR 26, have received that review, and are compliant with applicable ethics requirements. For certain studies that review may have included review by the HSRB. Descriptions of data sources as well as guidance on their use can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html and http://www.epa.gov/pesticides/science/post-app-exposure-data.html.

X. CONCLUSIONS

Since the occupational handler and postapplication risk estimates resulting from the new use of clopyralid do not exceed HED's level of concern, there are no occupational exposure issues that prevent registering clopyralid for use on apple. Further, there are no risks of concern associated with the existing use of clopyralid on turf. Finally, there are no ORE issues connected with amending the Stinger® Herbicide label to add Brassica, leafy greens to Crop Group 5B, without any change to the approved use pattern.